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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,255	11/27/2000	Kathleen E. Rodgers	00-448A	5684

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/723,255

Applicant(s)

RODGERS ET AL.

Examiner

Billy D Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is in response to Paper Number 6, filed 15 August 2002, wherein Applicants elected Group I, claims 1-16, drawn to a method of treating alopecia. Claims 12 and 14 were canceled and claims 1-11, 13 and 15-16 are under consideration by the examiner.

On page 1 (lines 5-9) Applicants made cross-reference to pending patent applications and should update the status.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent for treating alopecia utilizing a method of administering a compound, does not reasonably provide enablement for an agent which prevents alopecia. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described.

They are:

1. **the nature of the invention and the breadth of the claim,**

In the instant case, applicants are claiming a composition that is an agent for "preventing" alopecia. The nature of the invention is of a method of using a pharmaceutical for the treatment of a disease, i.e. alopecia.

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2. the state of the prior art,

As stated, however, the claim asserts that the composition is capable of preventing alopecia, or to keep from alopecia from happening. The state of the art does not teach the absolute prevention of alopecia, merely that the symptoms of the disease, such as hair loss (specification page 5, line 30), are/may be treated.

3. the predictability or lack thereof in the art,

Thus any claim to the prevention of alopecia is highly unpredictable given the current state of the art.

4. the presence or absence of working examples,

Furthermore, applicant states that the invention may be used in the prevention of alopecia (specification page 5, line 29) but does not provide examples as such. Whereas examples are given for the amelioration of alopecia, prevention is not taught.

5. the amount of direction or guidance present, the quantity of experimentation needed, and the level of the skill in the art.

Because neither the prior art nor the current application provide sufficient guidance to one of skill in the art as to the prevention of alopecia, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

Claims 2-4 and 6-9 are directed in part to an amino acid sequence comprising at least 3, 4, 5 or 6 contiguous amino acids of the sequence as set forth as SEQ ID NO: 41, which is the elected invention as required by 35 U.S.C. 121. The specification lacks adequate written description and does not teach any biological activity for a sequence having at least 3, 4, 5 or 6 contiguous amino acids of the sequence as set forth as SEQ ID NO: 41. There is no apparent discussion of what part(s) the polypeptide would have to remain such that biological activity was retained. Furthermore, one skilled in the art can not conclude that the Applicant was in possession of an amino acid sequence of i.e. 3 contiguous amino acids of the sequence as set

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forth as SEQ ID NO: 41 that would retain the same biological activity in the sense that the desired activity would convey repair of hair loss caused by alopecia and/or other activities of the SEQ ID NO: 41 protein pathways and/or to what, if all or some, treatments and/or tissue repairs an amino acid sequence of less than the full compliment sequence of SEQ ID NO: 41 conveys to a patient with alopecia caused hair loss.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13 and 15-16 are rejected for the recitation of the indefinite phrase "amount effective for treating." It is suggested that the indefinite phrase be removed as the claim is only enabled for treating alopecia (see above rejections) and this enablement would render the phrase indefinite. It is not clear whether "amount effective for treating" means full treatment or partial treatment. Applicants made the intended use clear in the preamble of claim 1 and need not repeat the intended use in the steps.

Conclusion

No claims allowed.

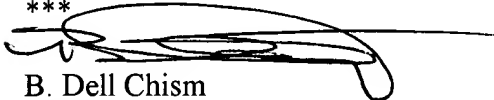
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



B. Dell Chism

09 September 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600